REMARKS

Claims 1-11, 16-23, and 25-27 are pending. Claims 1-10, 16-23, and 25-27 are withdrawn from consideration in the present application and are canceled herein without prejudice. Claim 11 is amended herein. New claims 28-30 are presented herein. Accordingly, amended claim 11 and new claims 28-30 are is presently under consideration.

Support for amendment to the claims is found throughout the specification and in the original claims. For the purposes of clarity, support found in the application is identified herein with respect to paragraph number as designated in United States Patent Application Publication No. 2006-0088537, which corresponds to the present application. Specifically, support for amendment to claim 11 is found, for example, in original claims 1, 6, and 11 and at paragraphs [0116] and [0121]. No issue of new matter is introduced by this amendment.

Support for new claims 28-30 is found throughout the specification and in the original claims. Support for new claim 28 is found, for example, in original claim 8. Support for new claims 29 and 30 is found, for example, in paragraphs [0116] and [0130]. No issue of new matter is introduced by these amendments.

The specification is amended herein to address the objections indicated below. No issue of new matter is introduced by these amendments.

Claim Objections

Claim 11 is objected to for containing subject matter that is drawn to a non-elected invention. Accordingly, claim 11 is amended herein to include the limitations of an antibody as defined in claim 6 and to delete reference to claim 6. It is, therefore, believed that the basis for the objection has been addressed and Applicant respectfully requests that the objection be withdrawn.

Specification

The Specification is amended herein to delete embedded hyperlinks and other forms of browser-executable code. The brief description of Figure 1 is objected to as improper disclosure of an amino acid sequence without a sequence identifier. The brief

description is amended herein to include the appropriate sequence identifier, namely SEQ ID NO: 1. In view of the above, it is believed that the objections to the Specification are obviated and may, therefore, be withdrawn.

Rejections under 35 USC § 112

Claim 11 is rejected under 35 USC § 112, first paragraph, for allegedly failing to comply with the enablement requirement. In view of the amendments to the claims and Applicant's arguments, the rejection, as it applied to claim 11 is respectfully traversed.

Claim 11 is amended to be directed to a method for the treatment of breast, lung and/or pancreatic cancer in a subject, which comprises administering to said subject a therapeutically effective amount of an antibody which is a monoclonal, chimeric, humanised or completely human antibody, wherein said antibody specifically binds to a NKCC1 polypeptide which consists of the amino acid sequence of SEQ ID NO: 1. Applicant asserts that a skilled practitioner would view the data presented in the specification as evidencing that the presently claimed method is practicable and, moreover, that the claimed method has a reasonable chance of success. More particularly, a skilled practitioner would understand that an antibody specific for NKCC1 would target NKCC1 present on breast, lung and/or pancreatic cancerous cells and would be able, based on the teachings of the specification, to make and test such an antibody without undue experimentation.

Applicant, furthermore, offers that the present invention represents the first disclosure of NKCC1 protein over-expression in breast, lung and/or pancreatic cancers. This discovery led to the realization of a new and credible utility of using an antibody directed against NKCC1, a previously unidentified protein target in these cancers, as a therapeutic. In view of the above, Applicant asserts that the claim to a method for the treatment of breast, lung and/or pancreatic cancer is commensurate with the present inventor's contribution to the art, i.e., the provision of a new target for breast, lung and/or pancreatic cancer treatment using an antibody specific for that target. This assertion is supported by mRNA over-expression data presented in Example 2, immunohistochemistry data presented in Example 3, and immunocytochemistry data presented in Example 4 of the specification. On the basis of the data presented in the

specification, a skilled practitioner would understand and readily believe and accept that an antibody specific for NKCC1, and in particular, a monoclonal, chimeric, humanised or completely human antibody would target NKCC1 protein present on cancerous cells since NKCC1 expression is increased in such cells. The making and testing of antibodies for the claimed use, while requiring some experimentation by a skilled artisan, does not require undue experimentation. A skilled artisan can readily make and test anti-NKCC1 antibodies using the teachings of the specification and his/her own knowledge and skills.

In particular, the specification teaches:

(i) techniques for the production of antibodies that bind to an antigen immunospecifically (in paragraphs [0116] to [0124]);

(ii) methods for selecting agents (including antibodies) for therapeutic use (in paragraphs [0163] to [0174]; and

(iii) antibody-drug conjugation techniques (in paragraph [0160].

That being the case, Applicant asserts that the instant claims are enabled by the specification. Accordingly, reconsideration and withdrawal of the above rejection are deferentially requested.

Claim 11 is also rejected under 35 USC § 112, first paragraph, for allegedly failing to comply with the enablement requirement with respect to an antibody that specifically binds to derivatives or fragments of SEQ ID NO: 1. In view of the amendments to the claims and Applicant's arguments, the rejection, as it applied to claim 11 is respectfully traversed.

The Examiner acknowledges that the specification is enabling for a method for the prophylaxis and/or treatment of breast, lung, and/or pancreatic cancer in a subject, which comprises administering to said subject a therapeutically effective amount of an antibody that specifically binds to SEQ ID NO: 1. The Examiner is of the opinion, however, that the specification is not enabling for a method for the prophylaxis and/or treatment of breast, lung, and/or pancreatic cancer in a subject, which comprises

administering to said subject a therapeutically effective amount of an antibody that specifically binds to SEQ ID NO: 1 or specifically binds to derivatives or fragments of SEQ ID NO: 1. As indicated herein, the claims are amended to delete reference to derivatives and fragments of SEQ ID NO: 1. It is, therefore, believed that this rejection is obviated.

Claim 11 is rejected under 35 USC § 112, first paragraph, for allegedly failing to comply with the written description requirement. More particularly, the Examiner maintains that the claim includes subject matter that is not described in the specification in such a way as to reasonably convey that the inventor had possession of the claimed invention at the time of filing. In view of the amendments to the claims and Applicant's arguments, the rejection, as it applied to claim 11 is respectfully traversed.

This rejection appears to be based on reference to derivatives and fragments of SEQ ID NO: 1 in claim 11. As indicated herein, the claims are amended to delete reference to derivatives and fragments of SEQ ID NO: 1. That being the case, it is believed that this rejection is obviated.

Claim 11 is further rejected under 35 USC § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner maintains that the claim includes subject matter that is not described in the specification in such a way as to reasonably convey that the inventor had possession of the claimed invention at the time of filing. In view of the amendments to the claims and Applicant's arguments, the rejection, as it applied to claim 11 is respectfully traversed.

This rejection appears to focus on reference to an antibody in claim 11 that specifically binds to an NKCCC1 polypeptide which comprises or consists of the amino acid sequence of SEQ ID NO:1 or is a derivative or fragment of SEQ ID NO: 1. As indicated herein, the claims are amended to delete reference to polypeptides comprising SEQ ID NO: 1 and derivatives and fragments of SEQ ID NO: 1. In light of the amendments to the claims, therefore, it is believed that this rejection is obviated.

The Examiner's comments regarding a number of references cited in connection with the above rejections are hereby acknowledged. In view of the amendments to the claims and arguments presented herein attesting to the teachings of the specification and level of skill in the art, Applicant believes that the issues raised in connection with these

references have been addressed. Applicant does, however, reserve the right to address each of these references in the future should this be necessitated during continued prosecution.

In view of the amendments to the claims and Applicant's arguments, therefore, reconsideration and withdrawal of the rejection of the claims under 35 USC § 112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 102

Claim 11 is rejected under 35 U.S.C. §102(e) as allegedly anticipated by Veiby [US2003/0068636, June 27, 2001]. In view of Applicant's arguments presented herein, the rejection as it applied to claim 11 is respectfully traversed.

Responsive thereto, Applicant asserts that Veiby discloses no less than 66 marker gene sequences which were identified by transcription profiling. See Tables 1-5. The marker gene sequences are indicated as being implicated in breast or ovarian cancer. Table 2, in particular, lists markers which were apparently upregulated in breast cancer at the transcriptional level. See, for example, paragraph [0023] for corroboration of this assertion. SEQ ID NO: 74 (which is 100% identical to NKCC1), however, is listed in Table 3 where the encoding nucleotide sequence was found to be upregulated in ovarian cancer. See, for example, paragraphs [0023] and [0330]. Accordingly, the Veiby application should, at best, be viewed as teaching antibodies to NKCC1 and treatment of ovarian cancer, not breast cancer, with therapeutic antibodies to NKCC1 in paragraphs [0186] and [0199] of the specification. That being the case, a skilled person would not contemplate selecting the gene sequence encoding NKCC1 from the list presented in Table 3 because this table lists ovarian cancer markers that are transcriptionally upregulated, not breast cancer markers.

Moreover, Applicant also asserts that disclosure of the 66 upregulated sequences offers no more than a mere 'laundry list' of nucleotide sequences that show differential expression in various cancers at the **RNA** level and that a skilled person receives no guidance from Veiby as to which of these markers from the speculative list one should select. Indeed, no guidance is presented regarding whether any of these "markers" are upregulated such that increased levels of protein are expressed in a cancer cell. In the

absence of such guidance, Applicant asserts that the Veiby patent application is a non-enabling reference with respect to a method directed to treatment of any cancer using any therapeutic antibody. Stated differently, Veiby fails to teach if any of the proteins corresponding to the 66 upregulated genes is upregulated in any cancer, including either of ovarian or breast cancer. A skilled practitioner would, therefore, view the information presented in Veiby as only an invitation to experiment. It is, moreover, especially non-enabling with respect to treatment of breast cancer with therapeutic antibodies to NKCC1 because it fails to teach a nexus between upregulation of NKCC1 and breast cancer.

That being the case, Veiby fails to teach a recited element of the instant claims. In view of Applicants' arguments, reconsideration and withdrawal of the rejection of claim 11 are deferentially sought.

In view of the amendments to the claims and Applicants' arguments, the Examiner is respectfully requested to reconsider the validity of the rejection of the claims under 35 U.S.C. §102 and withdraw the rejection.

Information Disclosure Statement

The Examiner has indicated that a compact disc (CD) can not be used to submit an Information Disclosure Statement (IDS) listing or copies of documents cited in an IDS. The two references Applicant attempted to submit via CD are exceedingly large documents, indeed the WO 01/22920A2 patent application is 9,787 pages long. The intent of Applicant's submission of these references on a CD was, therefore, to expedite delivery and entry of these documents into the record. In that the Examiner maintains that submission of these references via CD is improper, Applicant will review the matter so as to determine how best to submit these references for consideration in a Supplemental IDS which will be forthcoming.

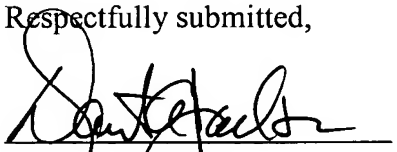
Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,



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Date: October 29, 2007

Enclosure: Petition for a One Month Extension of Time